IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(68603.507DV2)

Applicant:

Sullivan et al.

Art Unit:

TBA

Serial No.:

TBA

Examiner:

TBA

Filing Date: June 27, 2003

Title:

In Vivo Induction for Enhanced Function of Isolated Hepatocytes

Mail Stop: Patent Application

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97, Applicants submit the references listed on the attached PTO Form 1449. Copies of the International Search Report and International Preliminary Examination Report for PCT application number PCT/US00/20113, corresponding to the priority application, are also enclosed for your reference. The submission of this statement is not a representation that a search has been made, or that no better or other relevant art exists. This submission is also not an admission that any of the cited references is, or is considered to be, material to patentability or that any of the cited references constitutes prior art to the invention. Moreover, the Applicants understand that the Examiner will make an independent evaluation of the cited publications.

This application is a divisional of co-pending application Serial No. 10/036,593, filed December 21, 2001, which is a divisional of Serial No. 09/621,921, filed July 24, 2000, now U.S. Patent No. 6,394,812, issued May 28, 2002, which claims the benefit of provisional application Serial No. 60/145,362, filed July 22, 1999.

Copies of the references listed on the attached PTO Form 1449 are not enclosed herewith as these references have been submitted in the priority cases. However, copies can be provided upon request.

EXPRESS MAIL LABEL NO. EV 225204597US DATE OF DEPOSIT 27 June 2003

BOSTON 1693922v1

This statement is being filed before the mailing of a first Office Action on the merits. Therefore, no fees are believe to be due in connection with this submission. However, please charge any underpayments or credit any overpayments to Deposit Account No. <u>08-0219</u>.

Respectfully submitted,

HALE AND DORR LLP

Alison E. Corkery Registration No. 52,770 Attorney for Applicant

Dated: $\frac{6}{27}/03$

60 State Street Boston, MA 02109 (617) 526-6000 (617) 526-5000 (fax)

- 2 -

Application Number Subt. For, PTO-1449 Docket Number 68603-507DV2 **TBA** INFORMATION DISCLOSURE IN AN APPLICATION Applicant Sullivan, et al. (Use several sheets if necessary) Filing Date Group Art Unit TBA OF 2 Sheet 1

U.S. Patent Documents						
EXAMINER INITIAL	1 11016		NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,030,105	7/9/1991	Kuri-Harcuch, et al.			
	5,445,956	8/29/1995	Hammock, et al.			
	5,466,696	11/14/1995	Woolf			
	5,506,131	4/9/1996	Harris, et al.			
	5,576,207	11/19/1996	Reid, et al.			
	5,866,420	2/2/1999	Talbot, et al.			
	5,869,243	2/9/1999	Jauregui, et al.			
	6,127,117	10/3/2000	Morris, et al.			

Foreign Patent Documents							
EXAMINER	DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
INITIAL	NUMBER	DATE	COUNTRY	CLASS		YES	NO
				1	1		
			 		1		
					+		
					 		
		i			1		
				-+	 		

[Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)
	A 1	Baron et al. Effects of 3-methylcholanthrene, ß-naphthoflavone and phenobarbital on the 3-methlycholanthrene-inducible isozyme of cytochrome p-450 within centrilobular, midzonal and periportal hepatocytes (1982) J. Biol. Chem., Vol. 257, No. 2, pages 953-7.
	A 2	Morel et al. Preferntial increase of glutathione s-transferase class α transcripts in cultured human hepatocytes by phenobarbital, 3-methylcholanthrene, and dithiolethiones (1993) Cancer Research, Vol. 53, pages 231-234.
	A 3	Nishibe et al., Effects of phenobarbital and other model inducers on cytochrome p450 isozymes in primary culture of dog hepatocytes (1993) Xenobiotica, Vol. 23, No. 6, pages 681-692.
	A4	van't Klooster et al., Cytochrome p450 induction and metabolism of alkoxyresorufins, ethylmorphine and testosterone in cultured hepatocytes from goats, sheep and cattle (1993) Biochemical Pharmacology, Vol. 46, No. 10, pages 1781-1790.
	A5	Monshouwer et al., Characterization of cytochrome p450 isoenzymes in primary cultures of pig hepatocytes (Dec. 1998) Toxicology in Vitro, Vol. 12, pages 715-723.

EXAMINER	DATE CONSIDERED			
EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.				

Subt. For, PTC	ORMATION I			Docket Number Application Number 68603-507DV2 TBA		
IN AN APPLICATION (Use several sheets if necessary)				Applicant Sullivan, et al.		
				Filing Date	Group Art Unit	
Sheet	2	OF	2		TBA	

	A6	Silva et al., Induction of cytochrome-p450 in cryopreserved rat and human hepatocytes (June 1, 1999) Chemico-Biological Interactions, Vol. 121, pages 49-63.
	B1	Cottrell et al., Strain specific enhancement or inhibition of coumarin hepatotoxicity in mice following pretreatment with two different liver enzyme inducing agents (1996) Fundamental and Applied Toxicology, Vol. 34, pages 47-55.
	B2	Asaka et al., Localization of xenobiotic responsive element binding protein in rat hepatocyte nuclei after methylcholanthrene administration as revealed by in situ southwestern hybridization (1998) J. of Histrochem. & Cytochem., Vol. 46, No. 7, pgs 825-832.
	B 3	Oinonen et al., Pretranslational induction of cytochrome P4501 A enzymes by ß-napthoflavone and 3-methylcholanthrene occurs in different liver zones (1994) Biochemical Pharmacology, Vol. 48, No. 12, pages 2189-2197.
	B4	
	B5	
	B6	
	B7	
	B8	
	B9	
	B10	
	B11	
	B12	
	B13	
	B15	
<u> </u>	C1	
	C2	
	C3	
	C4	
	C5	
ļ	C6	
ļ	C7	
	C8	
[C9	
	C10	
	C11	
	C12	
	C13	
	C14	
	C15	
	C16	

EXAMINER	DATE CONSIDERED					
EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.						